



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

January 22, 2001

MEMORANDUM

SUBJECT: Butylate. (Chemical ID No. 041405, Case No. 0071). Dietary Risk Analysis for the HED Revised Human Health Assessment. No MRID #. DP Barcode No. D270811.

FROM: Felecia Fort, Chemist  
Reregistration Branch I  
Health Effects Division (7509C)

THRU: Michael Doherty, Chemist and Manying Xue, Chemist  
Dietary Exposure Science Advisory Council  
and  
Whang Phang, Ph.D., Branch Senior Scientist  
Reregistration Branch I  
Health Effects Division (7509C)

TO: Bentley Gregg, Chemical Review Manager  
Reregistration Branch 3  
Special Review and Reregistration Division (7508C)

BACKGROUND/ACTION REQUESTED

The Health Effects Division (HED) has been asked to conduct a dietary risk analysis for the active ingredient, butylate (S-ethyl diisobutyl thiocarbamate) in association with the human health risk assessment for the Reregistration Eligibility Document (RED). Acute and chronic assessments are required. The supported (reassessed) tolerances include the following crops [40 CFR 180.232]: field corn including popcorn (0.1 ppm) and sweet corn (0.1 ppm). The registered uses of butylate are classified as Category 3 of 40 CFR 180.6(a) with respect to residues in meat, milk, poultry and eggs; therefore, tolerances are not required for livestock commodities.

CONCLUSIONS/SUMMARY

Tier 1 analyses using tolerance level residues and 100% crop treated (%CT) were conducted for both the chronic and acute assessments. The analyses show that the acute Tier 1 is deterministic dietary exposure and risk estimates are not of concern for all population subgroups considered. The estimated exposure at the 95<sup>th</sup> percentile consumed is < 1% of the acute Population Adjusted Dose (aPAD). Likewise, chronic dietary exposure and risk were not of concern with less than 1% of the chronic Population Adjusted Dose (cPAD) consumed for all population subgroups.

These assessments are considered to be conservative since they are based on tolerance level residues and 100% CT.

## **DETAILED CONSIDERATIONS**

### **Toxicology Information**

The doses and endpoints for dietary risk assessment selected by the HED Hazard Identification Assessment Review Committee (HIARC) were discussed in detail in the P.Chin memorandum dated 8/7/98. The HIARC established an acute endpoint for females of reproductive age (females 13+ years old) and the general population (including infants and children). A summary of this information is presented in Table 1.

The HED FQPA Safety Factor Committee determined that the 10x Safety Factor should be removed since: 1) the toxicology data base is complete; 2) the developmental and reproductive toxicity data did not indicate increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure; 3) unrefined dietary exposure estimates (assuming all commodities contain tolerance level residues) will overestimate dietary exposure; 4) modeling data are used for ground and surface source drinking water exposure assessments resulting in estimates considered to be upper-bound concentrations; and 5) there are currently no registered residential uses for Butylate. (B. Tarplee, 8/27/98).

The doses and toxicological endpoints selected for dietary exposure scenarios are summarized in Table 1.

**Table 1. Summary of Endpoints and Doses for Butylate.**

<b>EXPOSURE SCENARIO</b>	<b>Population</b>	<b>DOSE (mg/kg/day)</b>	<b>RfD PAD (mg/kg/day)</b>	<b>ENDPOINT</b>	<b>STUDY</b>
Acute Dietary	Female 13+	NOEL=40 UF=100 FQPA SF = 1	aRfD = 0.4 aPAD = 0.4	Decreased fetal weights and increased incidences of misaligned sternebrae	Developmental–rat
	General population (including infants and children)	NOEL=600 UF=100 FQPA SF = 1	aRfD = 6 aPAD = 6	Sciatic nerve effects, neuronal cell necrosis, body weight decrease, and clinical signs of toxicity	Acute neurotoxicity–rat
Chronic Dietary	All populations	NOEL=5 UF=100 FQPA SF = 1	cRfD = 0.05 cPAD = 0.05	Increased relative liver weight in male dogs	12-Month feeding–dog

### **Residue Data**

Butylate (S-ethyl diisobutylthiocarbamate) is a selective herbicide registered for use on field corn, sweet corn, and popcorn. Tolerances for residues in/on corn commodities are expressed in terms of butylate *per se* [40 CFR §180.232]. No tolerances have been established for residues of butylate in animal commodities [40 CFR §180.6(a)(3)].

Adequate field trial data are available. Butylate was not detected in any sample (250 corn grain or whole ear samples and 200 samples of field corn forage and fodder; <0.02 to <0.05 ppm).

Tolerances of 0.1 ppm will be used for all commodities and food forms in the dietary analysis.

### **Processing Factors**

Corn grain and sweet corn cannery waste processing studies indicate that residues of butylate do not concentrate in processed food/feed items.

### **Consumption Data**

HED conducts dietary risk assessments using the Dietary Exposure Evaluation Model (DEEM™ Version 7.075), which incorporates consumption data generated in USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1989-1992. Consumption data are averaged for the entire U.S. population, and within population subgroups such as "all infants" to support chronic risk assessment, but retained as individual daily consumption data points to support acute risk assessment.

For chronic risk assessments, residue estimates for foods (e.g. apples) or food-forms (e.g. apple juice) of interest are multiplied by the averaged consumption estimate of each food/food-form of each population subgroup. Exposure estimates are expressed in mg/kg bw/day and as a percent of the cPAD.

For acute risk assessments, a food consumption distribution is calculated for each population subgroup of interest based on one day consumption data. The consumption distribution can be multiplied by a residue point estimate for a deterministic (Tier I/II type) exposure/risk assessment, or used with a residue distribution in a probabilistic (Monte Carlo) type risk assessment. Exposure estimates are expressed in mg/kg bw/day and as a percent of the aPAD.

### **Results**

The analyses show that the acute dietary exposure and risk estimates are not of concern for all population subgroups considered. The estimated exposure at the 95<sup>th</sup> percentile in the Tier 1 assessment consumed is < 1% of the acute Population Adjusted Dose (aPAD). Likewise, chronic dietary exposure and risk were not of concern with less than 1% of the chronic Population Adjusted Dose (cPAD) consumed for all population subgroups.

These assessments are considered to be conservative since they are based on tolerance level residues and 100% CT.

Table 3. Summary of Butylate Acute and Chronic Dietary Exposure and Risk Estimates.

Population Subgroup	Chronic Assessment <sup>1</sup>		Acute (95 <sup>th</sup> %ile) <sup>2</sup>	
	Exposure (mg/kg/day)	% cPAD	Exposure (mg/kg/day)	% aPAD
General US Population	0.000116	<1	0.000377	<1
All infants	0.000214	<1	0.000645	<1
Children 1-6 years old	0.000274	<1	0.000768	<1
Children 7-12 years old	0.000206	<1	0.000534	<1
Females 13-50 years old	0.000085	<1	0.000247	<1
Males 13-19 years old	0.000142	<1	0.000383	<1
Males 20+ years old	0.000085	<1	0.000250	<1
Seniors 55+	0.000068	<1	0.000205	<1

1 The chronic PAD (cPAD) is 0.05 mg/kg/day for all subgroups

2 The acute PAD is 0.4 mg/kg/day for females 13+ and 6 mg/kg/day for the general U.S. population including infants and children.

## Attachments

Attachment 1	Residue File
Attachment 2	Chronic Dietary Assessment- Tier 1 (Tolerance Level and 100% CT)
Attachment 3	Acute Dietary Assessment - Tier 1 (Tolerance Level and 100% CT)

cc: FFort, LaShonia Richardson (HED/CEB1); List A Rereg. File  
7509C:FFort:RRB1:CM2:Rm 722H:703 305-7478: 12/27/00

**Residue File**

U. S. Environmental Protection Agency

Ver. 7.075

DEEM Chronic analysis for BUTYLATE

1989-92 data

Residue file: C:\\$MyFiles\Butylate\chronic1.RS7

Adjust. #2 NOT used

Analysis Date 12-21-2000

Residue file dated:

12-21-2000/08:11:34/8

Reference dose (RfD) = 0.05 mg/kg bw/day

```

-----
Food Crop                               RESIDUE
Adj. Factors
Code  Grp  Food Name                     (ppm)          #1
#2
-----
-----
237 15   Corn/pop                        0.100000       1.000
1.000
238 15   Corn/sweet                       0.100000       1.000
1.000
266 15   Corn grain-endosperm                0.100000       1.000
1.000
267 15   Corn grain-bran                     0.100000       1.000
1.000
268 15   Corn grain/sugar/hfcs                 0.100000       1.000
1.000
289 15   Corn grain-oil                       0.100000       1.000
1.000
388 15   Corn grain/sugar-molasses             0.100000       1.000
1.000

```

## Chronic Results

U. S. Environmental Protection Agency

Ver. 7.075

DEEM Chronic analysis for BUTYLATE

(1989-92 data)

Residue file name: C:\\$MyFiles\Butylate\chronic1.RS7

Adjustment

factor #2 NOT used.

Analysis Date 12-21-2000/08:12:25

Residue file dated:

12-21-2000/08:11:34/8

Reference dose (RfD, Chronic) = .05 mg/kg bw/day

=====

### Total exposure by population subgroup

-----

Exposure Total

Percent of Population Subgroup	mg/kg body wt/day
-----	-----
U. S. Population (total) 0.2%	0.000116
U. S. Population (spring season) 0.2%	0.000114
U. S. Population (summer season) 0.2%	0.000122
U. S. Population (autumn season) 0.2%	0.000116
U. S. Population (winter season) 0.2%	0.000110
Northeast region 0.2%	0.000106
Midwest region 0.2%	0.000124
Southern region	0.000121

0. 2%	
Western region	0. 000107
0. 2%	
Hispanics	0. 000118
0. 2%	
Non-hispanic whites	0. 000113
0. 2%	
Non-hispanic blacks	0. 000133
0. 3%	
Non-hispanic/non-white/non-black	0. 000104
0. 2%	
All infants (< 1 year)	0. 000214
0. 4%	
Nursing infants	0. 000052
0. 1%	
Non-nursing infants	0. 000282
0. 6%	
Children 1-6 yrs	0. 000274
0. 5%	
Children 7-12 yrs	0. 000206
0. 4%	
Females 13-19 (not preg or nursing)	0. 000111
0. 2%	
Females 20+ (not preg or nursing)	0. 000074
0. 1%	
Females 13-50 yrs	0. 000085
0. 2%	
Females 13+ (preg/not nursing)	0. 000083
0. 2%	
Females 13+ (nursing)	0. 000094
0. 2%	
Males 13-19 yrs	0. 000142
0. 3%	
Males 20+ yrs	0. 000085
0. 2%	
Seniors 55+	0. 000068
0. 1%	
Pacific Region	0. 000101
0. 2%	

-----  
-----

**Acute Results**

U. S. Environmental Protection Agency

Ver. 7.075

DEEM ACUTE analysis for BUTYLATE

(1989-92 data)

Residue file: chronic1.RS7

Adjustment

factor #2 NOT used.

Analysis Date: 12-21-2000/08:14:34

Residue file dated:

12-21-2000/08:11:34/8

Acute Pop Adjusted Dose (aPAD) varies with population; see individual reports

Daily totals for food and foodform consumption used.

Run Comment: "Acute 6.0 mg/kg for gen pop. 0.4 mg/kg for females 13+ "

=====

**Summary calculations (per capita):**

99.9th Percentile		95th Percentile		99th Percentile	
Exposure	% aPAD	Exposure	% aPAD	Exposure	% aPAD
-----					
U. S. Population:					
		0.000377	0.01	0.000690	0.01
0.001248	0.02				
All infants:					
		0.000645	0.01	0.000975	0.02
0.001776	0.03				
Nursing infants (<1 yr old):					
		0.000240	0.00	0.000381	0.01
0.000423	0.01				
Non-nursing infants (<1 yr old):					
		0.000656	0.01	0.001099	0.02
0.001770	0.03				
Children 1-6 yrs:					
		0.000768	0.01	0.001175	0.02
0.001775	0.03				
Children 7-12 yrs:					
		0.000534	0.01	0.000749	0.01
0.001167	0.02				
Females 13+ (preg/not nursing):					

		0.000215	0.05	0.000308	0.08
0.000409	0.10				
Females 13+ (nursing):					
		0.000312	0.08	0.000383	0.10
0.000417	0.10				
Females 13-19 (not preg or nursing):					
		0.000304	0.08	0.000555	0.14
0.000752	0.19				
Females 20+ (not preg or nursing):					
		0.000216	0.05	0.000407	0.10
0.000752	0.19				
Females 13-50 yrs:					
		0.000247	0.06	0.000428	0.11
0.000735	0.18				
Males 13-19 yrs:					
		0.000383	0.01	0.000665	0.01
0.001047	0.02				
Males 20+ yrs:					
		0.000250	0.00	0.000402	0.01
0.000640	0.01				
Seniors 55+:					
		0.000205	0.00	0.000333	0.01
0.000751	0.01				